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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,763	12/21/2001	John Robert Tagg	512585-2001	5286

7590 11/14/2002

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EXAMINER

MELLER, MICHAEL V

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 11/14/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/913,763

Applicant(s)

TAGG ET AL.

Examiner

Michael V. Meller

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 24-26 and 41-46 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3 is/are allowed.
- 6) ☒ Claim(s) 1,2,4-23 and 27-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

The restriction requirement is maintained for the reasons of record. Claims 24-26 and 41-46 remain withdrawn from further consideration by the examiner as being drawn to non-elected subject matter.

Oath/Declaration

The oath continues to be improper. Applicants' acknowledgement is noted.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 4-23 and 27-40 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant argues that one to three amino acid deletions, insertions or substitutions are particularly contemplated in claim 4 and that such modified versions of the claimed protein are fully disclosed at certain points in the specification. Applicant has only shown that they possessed the specific SEQ ID NO: 3 at the time the invention was made. They have not shown that they were in possession of any and all deletions, insertions or substitutions of SEQ ID NO: 3.

Thus, the rejection is maintained.

Claims 21 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims continue to be indefinite since a microorganism such as the ones recited on the bottom of page 16 of the specification do in fact express both of the antibacterial agents, thus these claims (claims 21 and 22) do not further limit the claims that they depend from.

Claim 1 needs to have the "S." in "*S. salivarius*" spelled out. Further, it is confusing in this claim why there are two "isolated". The claim should simply read, "An antibacterial protein isolated from". Also it is confusing how the phrase, "or an antibacterial fragment or variant thereof which variant has greater than 80 % amino acid sequence homology with said protein", the whole protein is 25 amino acids (SEQ ID NO: 3). It is not clear what applicant is comparing this to, the SEQ ID No: 1 or SEQ ID

NO:3 ? 80 % of what ? This claim is very confusing. An antibacterial fragment would read on SEQ ID NO: 1 ? The claim does not clearly define what the invention is.

Claim Rejections - 35 USC § 102

Claims 1, 2, 4-15, 21-23 and 27-40 stand rejected under 35 U.S.C. 102(b) as being anticipated by Caufield et al.

Applicants' comments are noted but as is noted in the attached computer search there is indeed a 86.9 % sequence match. Such a percentage match clearly meets applicants claims, thus the claims are properly rejected under this section.

Claims 1, 2, 4-23 and 27-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caufield et al.

The teachings of Caufield are above.

Caufield does not explicitly teach some of the specific formulations recited in claims 16-20 but Caufield does teach that the claimed protein can be used in food and the like, col. 18-19.

Thus, it is well within the purview of the skilled artisan to use the claimed protein in formulations such as yogurt, milk, chewing gum and the like since these are commonly used foods and drinks. To pick particular foods and drinks are simply the choice of the artisan in an effort to optimize the desired results.

Claims 1, 2, 4-11, 13, 21-23 and 27-40 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ross et al., Tagg, Sanders, Jr. et al., Matsushiro or Kawai et al.

Applicant argues that these references do not teach the claimed protein. Applicant particularly argues that the references do not teach Salivaricin B, but Salivarcin B is not specifically claimed. The references teach the same microorganism and proteins therefrom, thus the claimed protein is taught. It is inherent to the microorganism that since it is the same organism it will produce the same protein.

Claims 1, 2, 4-23 and 27-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ross et al., Tagg, Sanders, Jr. et al., Matsushiro, or Kawai et al. taken with Caufield et al.

Applicant's arguments are above. Caufield is cited to show that the claimed protein can be used in food and the like, col. 18-19.

Thus, it is well within the purview of the skilled artisan to use the claimed protein in formulations such as yogurt, milk, chewing gum and the like since these are commonly used foods and drinks. To pick particular foods and drinks are simply the choice of the artisan in an effort to optimize the desired results.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 703-308-4230. The examiner can normally be reached on Monday thru Friday: 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Michael V. Meller
Examiner
Art Unit 1654

MVM
November 8, 2002